Department of Pesticide Regulation

Brian R. Leahy
Director

M E M O R A N D U M

Edmund G. Brown Jr.
Governor

TO: Susan McCarthy, M.S. **HSM-18002**
Environmental Program Manager II
Worker Health and Safety Branch

VIA: Kevin Solari *(original signed by K. Solari)*
Environmental Program Manager I
Worker Health and Safety Branch

FROM: Miglena Stefanova-Wilbur, Ph.D. *(original signed by M. Wilbur)*
Staff Toxicologist (Specialist)
Worker Health and Safety Branch
916-445-3607

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SUBJECT: BACKPACK USE OF NALED PRODUCTS IN CALIFORNIA

Introduction

Naled is an organophosphate insecticide used in public health and vector control programs for treatment of flies, mosquitoes and other insects. It is also used as an agricultural insecticide. Because of its toxicity as a dermal and eye corrosive agent, it is on the Federal list of restricted use pesticides, which in turn makes all naled products restricted materials in California.

Currently there are four naled products registered for end-use in California, having concentrations of the active ingredient (AI) between 36% and 87.4% (Table 1). The registrant for all four products is AMVAC. All products have the signal word DANGER and prohibit the use in and around homes either by homeowners or pest control operators. However, the labels for Dibrom 8 Emulsive, Dibrom Concentrate and Trumpet EC Insecticide make an exception for residential area use in wide-area pest abatement programs. All labels require closed mixing/loading (M/L) systems. The restricted status of the naled products means that only certified pesticide applicators, or those working under their supervision, are allowed to handle the products (40 CFR §152.160 – §152.175; Title 3, California Code of Regulations (3 CCR) section 6414).

Table 1. Naled products registered for end use in California as of August 2018.

Product (year of most recent CA label)	AI %	Backpack and other hand-held equipment present on the label	Other information (as specified on labels)
Dibrom Concentrate (2015)	87.4	No information	Dilute ground application requires application vehicle to be closed
Dibrom 8 Emulsive (2015)	62	Backpacks and hand-held foggers prohibited	Motorized ground ultra-low volume application for mosquito control requires enclosed cab
Trumpet EC Insecticide (2016)	78	No information	Ground application requires enclosed cab
Fly Killer D (2008)	36	Lists mist blower	Use as a space spray for flies/mosquitoes

Regulatory history

In 2001, the Department of Pesticide Regulation (DPR) finalized an addendum to the Risk Characterization Document (RCD) for naled (DPR, 2001). Among other scenarios, the occupational use of backpack sprayers was identified as exposing the handlers (mixer/loader/applicator, M/L/A) to risks for short-term systemic adverse effects below the target margins of safety (Table 2). The RCD Addendum included an additional, backpack–applicator-only scenario, without the mixer/loader work activity. The risk estimates for this scenario were in the single digit Margins of Exposure (MOE) for localized and systemic effects (Tables 13-15 in DPR, 2001). This backpack–applicator-only scenario was not included in the present memorandum. In the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide, the U.S. Environmental Protection Agency (U.S.EPA) stated that, most often, the same person would be mixing/loading and applying pesticides. Subsequently, the Agency recommended the exposures to backpack M/L/A as more appropriate (U.S.EPA, 1998). Similarly, DPR lists only the M/L/A backpack scenario in its PHED guidance document (Beauvais *et al*., 2007). The Risk Management Directive (RMD) issued by DPR in 2003, directed the Department to mitigate the unacceptable risks to backpack applicators (Gosselin, 2003).

Table 2. Margins of exposure (MOE) for occupational exposures to naled associated with non-agricultural use by backpack M/L/As in California. Data from Tables 13 and 15 in the RCD addendum (DPR, 2001) for localized and systemic effects, respectively. The MOEs below the target are marked in **bold**.

Backpack Scenario	MOE for systemic exposure (target MOE 100)		MOE for short-term (acute) localized exposure (target MOE 10)										
	Short-term (acute)	Long-term (sub-chronic)	Head	Neck	Upper arm	Chest	Back	Fore arm	Thighs	Lower leg	Feet	Hands	Whole
M/L/A[a]	**71**	124	769	38	55	3075	77	1538	1230	1025	NA[b]	NA[b]	186

[a] M/L/A = mixer/loader/applicator.
[b] NA = Not available (Appendix 8A and Addendum 2 in: Dong and Haskell, 2000).

The Interim Reregistration Eligibility Decision (IRED) for organophosphates (U.S.EPA, 2006) finalized the IRED for naled (U.S.EPA, 2002). The IRED states that in order to "mitigate risks to agricultural workers: …Require enclosed cabs for ground application or enclosed cockpits for aerial application, for all agricultural uses and public health uses involving control of mosquitos and black flies. … Delete backpack sprayers and hand-held foggers." (U.S.EPA, 2002).

Label overview

Three of the four current California labels for naled have ambiguous language regarding hand-held equipment, including backpack sprayers and hand-held foggers (Table 1):

1. The labels for Dibrom Concentrate and Trumpet EC Insecticide state "Vehicles used to apply …. must be kept closed during application", but do not explicitly prohibit the use of hand-held equipment.
2. The Fly Killer D label states: "Applicators using motorized ground-equipment must use an enclosed cab". The label also specifically states an application rate for adult mosquito treatment with mist blower equipment. Additionally, directions for use of Fly Killer D as a space spray to walls, floors, etc., for control of mosquitoes, flies, and other insects (e.g., in and around livestock quarters, feed lots and food processing establishments), specifically state an application rate of 5 teaspoons in 1 gallon of water (2 fl. oz. in 2.5 gallons of water (0.06 lbs AI) or 2 pints in 40 gallons of water). This recommended rate implies that some applications could be made on a small scale by using portable hand-held equipment (such as but not limited to backpack sprayers). In addition, the label-listed use of a mist blower for treatment of "vegetation around stagnant pools, marshy areas, ponds" does not exclude applications by backpack mist blowers: the top three hits of a Google search for "mist blower" return links to backpack equipment (search on 01/16/2018). The label requires that "Mixers, loaders, applicators and other handlers engaged in those handler activities for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment, must wear:
    - Protective eyewear (goggles, face shield, or safety glasses)
    - Coveralls over long-sleeve shirt and long pants
    - Chemical-resistant gloves
    - Chemical-resistant footwear plus socks
    - Chemical-resistant apron if exposed to the concentrate
    - Chemical-resistant headgear for overhead exposure
    - A respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23G), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, and HE prefilter."
3. The label for Dibrom 8 Emulsive states: "Use of hand-held foggers and back-pack sprayers is prohibited." In addition, the label requires use of an enclosed cab when motorized ground equipment is used.

The focus of this memorandum is on the possible backpack use of Fly Killer D for mosquito and fly control because the label language does not clearly prohibit the use of hand-held equipment, nor does it otherwise indicate exclusive use of motorized ground equipment. The other three naled products either explicitly prohibit hand-held equipment (Dibrom 8 Emulsive), or have a requirement for an enclosed cab for ground applications (Dibrom Concentrate and Trumpet EC Insecticide), indicating that these labels do not allow the use of hand-held equipment.

Risk assessment

The risks for localized adverse effects to backpack M/L/As of Fly Killer D calculated in DPR's Naled Risk Assessment Addendum (DPR, 2001) were all above the target MOE, while systemic effects from short-term (acute) exposures were estimated to be below the target MOE as shown in Table 2 (data from DPR, 2001).

However, the 2001 risk assessment addendum did not examine the risk of systemic effects while naled was being "open-poured" into a backpack and applied while wearing the current label-required personal protective equipment (PPE). I estimated the risk for systemic effects of naled exposure to backpack open-pour M/L/As using PHED Scenario #20 (Beauvais *et al*., 2007) and the currently accepted DPR methods (Beauvais *et al.*, 2007). Resultant MOEs were between 35 and 83 for short-term (acute) exposures and 96 to 230 for long-term (sub-chronic) exposures (Table 3). This estimate includes:

- Short-term exposures: 90% upper confidence limit (UCL) of the 95th percentile of daily exposure to head, body, feet, and hands;
- Long-term exposures: 90% UCL of the arithmetic mean of daily exposure to head, body, feet, and hands;
- Multipliers for calculating the 90% UCL are from Powell, 2007;
- Feet exposure was calculated as 52% of lower leg exposure: 0.52 is the calculated average ratio of feet/lower leg surface area for men and women (Table 6-4 in: U.S.EPA, 1997);
- PPE required by the Fly Killer D label when engineering controls cannot be used: coveralls over long pants and long-sleeved shirt, chemical-resistant gloves and boots, respirator, and face shield. Protection factors for using PPE are taken from HS-1612 (Thongsinthusak *et al.*, 1993);
- Mist blower application to "vegetation around stagnant pools, marshy areas, ponds", using 1.5 gallons of Fly Killer D in 100 gallons of spray solution, equivalent to 0.0525 lbs AI/gallon spray solution;
- Space spray application in and around livestock quarters, feed lots, and food processing establishments, using 2 pints of Fly Killer D in 40 gallons of spray solution, equivalent to 0.0219 lbs AI/gallon spray solution;
- Open-pour mixing/loading per Scenario #20 (Beauvais *et al.*, 2007);
- All other parameters included in the risk calculation of systemic adverse effects to naled exposure were as described in the Exposure Assessment Document (Dong and Haskell, 2000) and in the RCD addendum (DPR, 2001).

Table 3. Margins of exposure (MOE) for systemic effects for backpack M/L/A occupational exposures to Fly Killer D. Target MOE 100**.** The MOEs below the target are marked in **bold**.

Scenario	MOE This memorandum				MOE RCD addendum (DPR, 2001)	
	Space Spray		Mist Blower		Short-term (acute)	Long-term (sub-chronic)
	Short-term (acute)	Long-term (sub-chronic)	Short-term (acute)	Long-term (sub-chronic)		
Backpack M/L/A	**83**	230	**35**	**96**	**71**	124

Note that the current naled labels require closed system mixing/loading, which will reduce the M/L exposure. The degree of risk reduction by use of closed M/L system is difficult to estimate because the only PHED Scenario for backpack handlers (Scenario #20, M/L/A) used by DPR (Beauvais *et al.*, 2007) does not provide separate exposure estimates for the mixing/loading and the application activities.

Mitigation

The risk of naled exposure to backpack handlers estimated in this memorandum includes the applicable PPE required by the Fly Killer D label when engineering controls (e.g., enclosed cab) cannot be used: coveralls over long pants and long-sleeved shirt, chemical-resistant gloves and boots, a face shield, and a respirator. The risk mitigation for short-term exposures to a MOE $\geq$ 100 could be achieved by either a reduction in the work hours per day or a reduction in the amount of product in the spray solution, or by a combination of both factors (Table 4).

Table 4. Mitigation of short-term systemic exposures to occupational backpack handlers of Fly Killer D. Target MOE 100**.** The MOEs below the target are marked in **bold** and shaded.

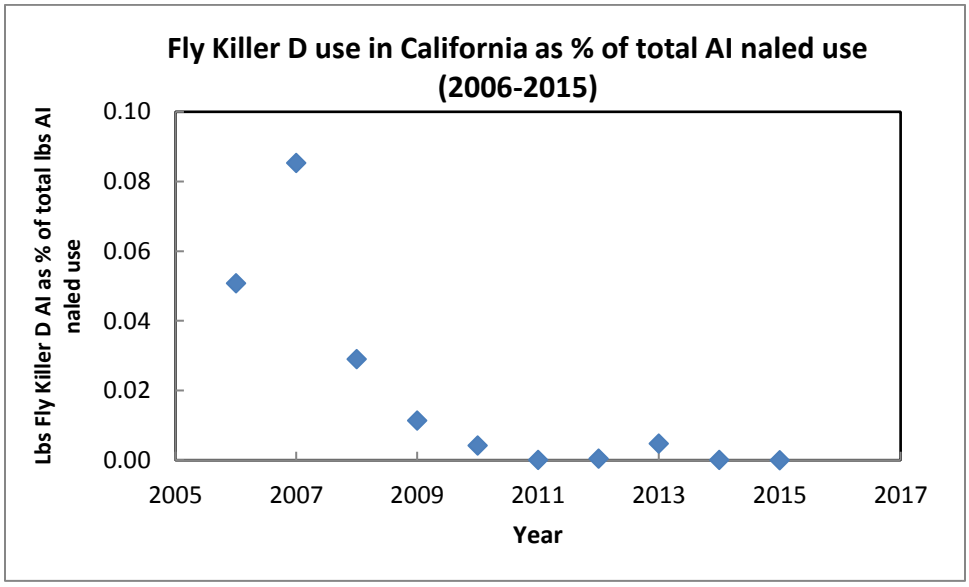
Backpack spray equipment	Application rate		MOE for short-term systemic effects						
			Work hours/day						
			8	7	6	5	4	3	2
Mist blower	Gallons of product/100 gal water	1.5[a]	**35**	**39**	**46**	**55**	**69**	**92**	138
		1.0	**52**	**59**	**69**	**83**	104	138	207
		0.5	104	118	138	166	207	276	414
Space spray	Pints of product/40 gal water	2.00[a,b]	**83**	**95**	111	133	166	221	332
		1.75	**95**	108	126	152	190	253	379

[a] Maximal application rate on Fly Killer D label.
[b] Equivalent to 2 fl. oz. in 2.5 gal water.

Pesticide use

The annual use of Fly Killer D as a percentage of all use of products with the AI naled in California is negligible and has declined over the past 10 years (Figure 1, DPR Pesticide Use Report http://www.cdpr.ca.gov/docs/pur/purmain.htm, query on 12/11/2017). No Fly Killer D uses were reported in 2015 (the latest year with available pesticide use records). No illnesses related to the product's use have been reported in California over the last 10 years (CA Pesticide Illness Surveillance Program query by Jennifer Ha, Worker Health and Safety Branch, August 8, 2018).

Figure 1. Fly Killer D use in California as percentage of total active ingredient (AI) naled use.



Conclusions

Naled is one of the insecticides of choice in mosquito abatement programs, primarily *via* aerial applications (https://www.cdc.gov/zika/vector/aerial-spraying.html, accessed 12/14/17; U.S.EPA, 2017). However, with the declining use of Fly Killer D over the last 10 years, this product poses a lesser risk for occupational exposure to certified handlers who may use backpack application equipment. Should the backpack use of the product increase for mosquito eradication in small-scale operations, this use scenario may have adverse effects on the pesticide handlers who use the product, unless limitations on work hours and/or maximal application rates are required as outlined above in Table 4. Use of a closed mixing system, as currently required by the product label, also reduces the risk of exposure, although this reduction could not be quantified for the reasons outlined above.

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References

Beauvais, S., Powell, S., and Zhao, W. 2007. Surrogate handler exposure estimates for use in assessments by the California Department of Pesticide Regulation. HS-1826. Worker Health and Safety Branch, DPR, California EPA. http://www.cdpr.ca.gov/docs/whs/pdf/hs1826.pdf.

Dong, M., and Haskell, D. 2000. Human Pesticide Exposure Assessment Naled (An Organophosphate Insecticide for a Variety of Agricultural and Non-Agricultural Uses). HS-1739. Worker Health and Safety Branch, DPR, California EPA. http://www.cdpr.ca.gov/docs/whs/pdf/hs1739.pdf.

DPR. 2001. Naled risk characterization document (RCD 99-03) first addendum. DPR, California EPA. http://www.cdpr.ca.gov/docs/risk/rcd/naled_add.pdf.

Gosselin, P. 2003. Naled risk management directive. May 2, 2003. http://www.cdpr.ca.gov/docs/emon/pubs/rm_directives/rmd_naled.pdf.

Powell, S. 2007. Recommended method for approximating confidence limits for upper bound and mean Exposure estimates from the pesticide handlers exposure database (PHED) to replace the method of HSM-02037. HSM-07004. Sacramento, CA: Worker Health and Safety Branch, DPR, California EPA. September 20, 2007. http://www.cdpr.ca.gov/docs/whs/memo/hsm07004.pdf.

Thongsinthusak, T., Ross, J., and Meinders, D. 1993. Guidance for the Preparation of Human Pesticide Exposure Assessment Documents. HS-1612. Sacramento, CA: Worker Health and Safety Branch, DPR, California EPA. http://www.cdpr.ca.gov/docs/whs/pdf/hs1612.pdf.

U.S.EPA. 1997. Exposure factors handbook. Office of Research and Development, US Environmental Protection Agency, Washington, DC. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=12464.

U.S. EPA. 1998. PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database, Version 1.1. Washington, DC: Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency.

U.S.EPA. 2002. Interim Reregistration Eligibility Decision for naled. EPA 738-R-02-008. https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-034401_31-Jul-06.pdf (accessed 01/12/2018).

U.S.EPA. 2006. Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the organophosphate pesticides, and completion of the Tolerance Reassessment and Reregistration Eligibility process for the organophosphate pesticides. https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-034401_31-Jul-06.pdf (accessed 01/12/2018).

U.S.EPA. 2017. Naled for mosquito control fact sheet. https://www.epa.gov/mosquitocontrol/naled-mosquito-control-fact-sheet, https://www.epa.gov/sites/production/files/2017-06/documents/revised_naled_web_qs_and_as-6-14-17.pdf (accessed 01/16/2018).